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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff,

v.

INTUITIVE SURGICAL, INC.,

Defendant.

Case No. 3:21-cv-03496-AMO

DEFENDANT INTUITIVE SURGICAL INC.'S TRIAL BRIEF

Date: November 25, 2024
Time: 11:00 a.m.
Courtroom: 10

The Honorable Araceli Martínez-Olguín

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INTRODUCTION[1]

In 1995, a small group of engineers and entrepreneurs invented a new way of doing surgery. Their invention was called the da Vinci, and the company they formed to bring that invention to the marketplace was called Intuitive Surgical. The founders of Intuitive took an enormous risk. Their invention cost hundreds of millions of dollars to develop. Before they could market the da Vinci, they had to prove to the FDA and other regulators that it was safe and effective to use with patients. And to sell the da Vinci to hospitals, they had to convince surgeons that it offered material advantages over alternative ways they had to perform the same surgical procedures—including traditional open surgery and minimally invasive laparoscopic surgery. Success on any dimension was far from guaranteed. And given the stakes involved with a new surgical device—literally, life and death—a single mistake could sink the company.

From Day One, Intuitive thus prioritized patient safety above all else. Intuitive built its business to compete in the marketplace by offering better, more innovative products that for at least certain patients and procedures could deliver a safer, faster, and less expensive choice for surgery. Intuitive has continued to compete in the same way ever since. After Intuitive succeeded in inventing and commercializing this new option for performing surgical procedures, it continued to invest billions of dollars in further developing and improving the da Vinci system.

"The successful competitor, having been urged to compete, must not be turned upon when he wins." *United States* v. *Aluminum Co. of Am.* ("*Alcoa*"), 148 F.2d 416, 430 (2d Cir. 1945) (Hand, J.). In this case, SIS is trying to misuse the antitrust laws to penalize Intuitive for having competed successfully, and to divert to itself a share of the profits Intuitive earned from its competitive success. SIS is not actually a competitor to Intuitive in any meaningful sense. SIS invented nothing. SIS took no risk. After Intuitive had already spent a quarter century and billions of dollars developing the da Vinci system, SIS began re-selling another company's product and service for performing unauthorized modifications to Intuitive's invention. Those modifications involved resetting the use counter on Intuitive's EndoWrist surgical instruments, to allow a given

[1] All references to "Ex." refer to exhibits to the Declaration of Paul D. Brachman in Support of Defendant's Trial Brief.

instrument to be used more times on more patients than what Intuitive had determined to be safe and had submitted clinical proof to the FDA to support. SIS did this without conducting any testing to confirm that what that other company (Rebotix) was doing was safe. SIS then chose to mislead its hospital customers about what it was offering them. SIS spread false and misleading information about the safety and quality of its offerings to convince customers to violate contracts they had knowingly and willingly entered into with Intuitive.

SIS chose not even to try to seek Intuitive's authorization for offering modified versions of Intuitive's products, or to provide Intuitive with clinical proof that such modifications were safe and effective for patients. SIS also chose not to invest the time or money to seek FDA clearance for the EndoWrist modification service it was offering, to prove to customers that it was safe. In effect, SIS asked everyone—Intuitive, doctors, patients—to take SIS's word for it that its service would be safe. And, by conducting no tests of its own, SIS itself took Rebotix's word for it on safety. SIS now comes to Court demanding that Intuitive pay SIS nearly half a billion dollars. And it claims that the antitrust laws entitle it to that lottery-jackpot recovery despite its having done little or nothing to actually compete.

In addition to being at odds with the most basic principles of antitrust law, SIS's case is grounded on a fundamental misconstrual of Intuitive's contracts and conduct. SIS alleges that Intuitive forces da Vinci customers to use Intuitive's replacement EndoWrists instead of EndoWrists that customers previously licensed from Intuitive and later had modified by a third party, in order to overcharge hospitals for EndoWrists. But Intuitive does not require hospitals to use only Intuitive's products and services, or prohibit use of all third-party products and services in conjunction with the da Vinci system. Rather, it says that hospitals may only use with Intuitive's systems those products and services that have been *authorized* or approved by Intuitive.

Intuitive has included provisions to this effect in its contracts with hospitals—sophisticated purchasers who freely contract for da Vinci systems knowing about these terms—ever since Intuitive first launched the da Vinci more than 25 years ago, *before Intuitive had any share of any market*, and before it could conceivably have excluded any third party from competing in any market. Intuitive includes those provisions in its contracts for good and valid business reasons.

Absent authorization and approval of modifications that third parties propose to make to Intuitive's products, Intuitive would have no way of ensuring patients' safety and the proper functioning of its da Vinci system. It would have no reliable way to protect itself against the substantial liability risks and costs associated with the potential for unauthorized third-party devices to cause injury to patients. And it would be putting in jeopardy the reputation for quality and safety that it has spent decades building with surgeons and patients alike.

Despite knowing that Intuitive's contracts required authorization to use third-party products and services with the da Vinci, SIS never sought to obtain Intuitive's authorization to modify EndoWrists. SIS never asked Intuitive how it might qualify to become authorized. SIS never did any work to prove itself qualified. Intuitive had consistently made clear it would not approve the use of third-party products and services that had not received 510(k) clearance from the FDA or provided independent clinical proof of safety and efficacy to Intuitive. Yet SIS never even tried to seek clearance from the FDA or to present Intuitive with any clinical evidence that the service SIS was offering to hospitals was safe.

In contrast to SIS, another third party—Iconocare, a subsidiary of Restore Robotics—sought *and received* FDA 510(k) clearance to reset the use counter on a particular EndoWrist instrument and market remanufactured versions of that EndoWrist to customers. And, after Iconocare received such clearance (becoming the first third party to do so), Intuitive made a public announcement clarifying to its customers and the entire marketplace that the use of these and any other 510(k) cleared remanufactured instruments would not breach a customer's service agreement or otherwise subject a customer to any adverse action from Intuitive.

Iconocare and Restore reached an agreement with each other to pursue FDA clearance in spring/early summer 2019. At essentially the same time, SIS made the choice to work with Rebotix, a company that previously had sought *and failed* to receive FDA clearance to remanufacture EndoWrists, meaning that it failed to prove to the FDA that its EndoWrist modification process—the *same* process that SIS offered to customers—was safe and effective. SIS also misled its customers, by, among other things, claiming its modified EndoWrists were safe and tested, without ever even seeing complete data or performing any tests of its own; by falsely

claiming modified EndoWrists would function just like new EndoWrists; and by falsely claiming that its so-called "repaired" EndoWrists would be returned to Intuitive's "original specifications," without even having access to those specifications.

In sum, Restore and Iconocare chose a path that required risk and investment but ultimately ended with an FDA-cleared product to which Intuitive made no objections. SIS, by contrast, chose a path with a company that had previously been rejected by the FDA, and thought it should be entitled to start immediately collecting what it claims would have been tens or hundreds of millions of dollars without taking any risk or proving its product safe. SIS also misled its customers about what was involved in its service, and then immediately brought an antitrust lawsuit seeking enormous money damages when its other corner-cutting tactics did not produce the easy money it hoped for.

The fact that third parties, as demonstrated by Iconocare, have a clear path available to be able to offer modified EndoWrists to customers without implicating Intuitive's contracts means as a matter of law that SIS cannot show that customers are forced to buy replacement EndoWrists from Intuitive, and thus that SIS cannot prove that Intuitive engaged in illegal tying or exclusive dealing. Moreover, even if it could prove such conduct, SIS cannot refute that Intuitive has legitimate procompetitive justifications for its authorization requirements. Additionally, because SIS took no steps to seek authorization or 510(k) clearance, SIS also cannot show that Intuitive's actions—rather than SIS's own business choices—caused SIS's alleged damages, or that its alleged losses constitute the type of injury the antitrust laws protect against.

Leaving aside the many independent legal defects with SIS's case, including those discussed in Sections I-V below, there are a host of factual reasons why the jury will be free to and should reject SIS's enormous damages claim. SIS's damages calculation, too, suffers from fundamental legal defects discussed in Section VI below.[2] And as noted in Section VII, Intuitive asserts counterclaims based on SIS's false and misleading statements and other misconduct.

[2] Intuitive does not contest that the relevant geographic market is the United States or that it sells its products in interstate commerce. Intuitive otherwise disputes SIS's ability to prove each and every required element of its claims, and expressly reserves all defenses to such claims. In this brief Intuitive focuses on what it contends are the key legal issues in the case. By not discussing a particular issue, however, Intuitive does not waive any claims, defenses or arguments.

CONTROLLING ISSUES OF LAW

I. SIS'S TYING CLAIM IS SUBJECT TO THE RULE OF REASON, NOT "PER SE ILLEGALITY."

SIS argues that Intuitive's alleged tying arrangement should be adjudged per se illegal. As set forth more fully in Intuitive's jury instruction brief (filed separately today), the jury will ultimately have to find the same elements whether it is instructed under a per se or rule of reason standard. SIS's argument for applying the "per se" label is thus superfluous and confusing. It is also legally baseless and wrong.

Only "certain" tying arrangements qualify for per se illegality. *Jefferson Parish Hosp. Dist. No. 2* v. *Hyde*, 466 U.S. 2, 9 (1984), *abrogated on other grounds by Ill. Tool Works Inc.* v. *Indep. Ink, Inc.*, 547 U.S. 28 (2006); *Blough* v. *Holland Realty, Inc.*, 574 F.3d 1084, 1088 (9th Cir. 2009). In its most recent tying cases, the Ninth Circuit has consistently applied the rule of reason or more generally discussed the required elements of tying without using the per se label. *Epic Games, Inc.* v. *Apple, Inc.*, 67 F.4th 946, 997-98 (9th Cir. 2023); *Aerotec Int'l, Inc.* v. *Honeywell Int'l, Inc.*, 836 F.3d 1171, 1178-80 (9th Cir. 2016); *Brantley* v. *NBC Universal, Inc.*, 675 F.3d 1192, 1197 (9th Cir. 2012). Hence, in order to trigger the per se label, SIS would need to provide some affirmative reason why *this particular case* qualifies as different from the vast majority of cases which are governed by the rule of reason. SIS has provided no such reason.

The allegation that Intuitive has market power (or monopoly power) in the purported market for minimally invasive soft tissue surgical ("MIST") robots cannot serve as a basis for applying the per se rule. Under Supreme Court precedent, "in *all* cases involving a tying arrangement, the plaintiff must prove that the defendant has market power in the tying product." *Ill. Tool Works*, 547 U.S. at 46 (emphasis added). Because market power in the tying market must be proven in all tying cases, including those governed by the rule of reason, Intuitive's alleged market power cannot be a basis for asserting that the per se rule applies.

Moreover, in its most recent tying case, *Epic*, the Ninth Circuit held that if per se illegality continues to apply for certain tying arrangements, it should be limited to circumstances where the tie is "plainly anticompetitive and lack[ing] . . . [in] any redeeming virtue such that it can be

conclusively presumed illegal." 67 F.4th at 997 (cleaned up). Here, this Court has already ruled that Intuitive has colorable arguments that its conduct "has certain benefits, including ensuring product reliability and minimizing risks to patients" and that the "conflicting evidence regarding the potential benefits of Intuitive's conduct is best left for a jury to weigh." Summary Judgment Order, Dkt. 204 at 18:20-22, 27-28.[3] In so ruling, the Court cited *NCAA* v. *Alston*, 594 U.S. 69, 97 (2021), and noted that it applied the rule of reason to determine such contested questions. Dkt. 204 at 17:25-19:8.[4] In light of the Court's ruling that there are legitimately contested questions of fact about the procompetitive justifications for the alleged tie, it would be erroneous to hold that the alleged tie is "plainly lacking in any redeeming virtue." *See Epic*, 67 F.4th at 997. The rule of reason thus should apply.

II. THE OPPORTUNITIES FOR THIRD PARTIES TO BECOME AUTHORIZED HAS IMPORTANT, AND CASE-DISPOSITIVE, DOCTRINAL IMPLICATIONS FOR THIS CASE.

A. SIS Cannot Establish Tying or Exclusive Dealing Based on Contract Provisions Requiring the Use of Authorized Third Parties.

Intuitive maintains it has not engaged in tying or exclusive dealing because it has not required hospitals to obtain EndoWrists exclusively from Intuitive. Instead, Intuitive requires hospitals not to use EndoWrists serviced or modified by *unauthorized* or *unapproved* third parties.[5] Further, Intuitive explicitly and repeatedly made clear what the criteria would be for a third party to be authorized within the meaning of the contract: they would have to receive FDA clearance or provide clinical evidence of the safety and efficacy of their processes.[6]

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[3] The Court denied summary judgment because the facts were not *undisputed* that Intuitive had proven a "nonpretextual 'procompetitive rationale[,]'" Dkt. 204 at 18:19-20 (citation omitted), but Intuitive submits that the evidence at trial will establish nonpretextual, procompetitive justifications for its conduct.

[4] The Court also noted, correctly, that SIS did not even "assert that the alleged restraints here are *per se* unreasonable." Dkt. 204 at 17:6-7. SIS's late-breaking decision to make that assertion now is baseless for the reasons discussed.

[5] *See, e.g.*, Ex. 1 at -2317 ("Intuitive does not have an obligation to provide Services (1) on any System where installation, repair, or adjustments have been made by an individual other than an Intuitive technician ***or an individual approved by Intuitive*** or (2) which are either necessary or desired as a direct or indirect result, in whole or in part, of ***unauthorized repair, modification, disassembly, alteration, addition to, subtraction from, reconfiguration***, or misuse of the System, or negligence or recklessness on the part of Customer.").

[6] *See, e.g.*, Ex. 2 at -6092 ("If you allege that you received FDA clearance for the modifications to the *EndoWrist*® instruments described herein or possess clinical proof that your service process returns the modified instruments to [] 'a production equivalent qualification' and/or that additional

The possibility that third parties would obtain authorization was not merely hypothetical or illusory. After Iconocare received FDA clearance, Intuitive announced publicly that "Intuitive will not void its service contract with, cease doing business with, or consider it a breach of contract by a customer in the United States who chooses to purchase remanufactured instruments that have been remanufactured by a third party pursuant to and in compliance with a 510(k) clearance or equivalent granted by the FDA."[7] *See* Ex. 6. And, Intuitive has long validated and approved the use of other third-party products and services in connection with the da Vinci system, when it is able to determine their safety and efficacy.

"A tying arrangement is 'an agreement by a party to sell one product but only on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that product from any other supplier.'" *Eastman Kodak Co.* v. *Image Tech. Servs., Inc.*, 504 U.S. 451, 461-62 (1992) (citation omitted). In such an arrangement, the seller "force[s] the buyer into the purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms." *Epic*, 67 F.4th at 995 (quoting *Jefferson Parish*, 466 U.S. at 12). "Exclusive dealing involves an agreement between a vendor and a buyer that prevents the buyer from purchasing a given good from any other vendor." *Allied Orthopedic Appliances Inc.* v. *Tyco Health Care Grp. LP*, 592 F.3d 991, 996 (9th Cir. 2010).

When arising from the same alleged anticompetitive conduct, courts often consider tying and exclusive dealing claims under the same analytical framework. *E.g.*, *Eastman* v. *Quest Diagnostics Inc.*, 724 F. App'x 556, 558 n.1 (9th Cir. 2018) ("[Plaintiffs'] allegations of 'tying' and 'exclusive dealing' with medical providers are essentially the same exclusionary practice for § 2 purposes, and therefore the analysis set forth for exclusive dealing also applies to the tying claim for the purposes of § 2."); *Dream Big Media Inc.* v. *Alphabet Inc.*, 2024 WL 3416509, at *5

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use does not affect the safety or performance of the instruments, provide proof of the same[.]"); Ex. 3 at -8444 (same); Ex. 4 at -5583_(same); Ex. 5 at -5279 ("If you allege that you or your service centers received FDA clearance for the modifications to the EndoWrist® instruments described herein or possess clinical proof that your service process returns the modified instruments to a 'production equivalent qualification' and/or that additional use does not affect the safety or performance of the instruments, provide proof of the same.").

[7] SIS has argued that Intuitive's motive in making this statement was its settlement agreements with Restore and Rebotix. That is both irrelevant and unsupported by any evidence.

(N.D. Cal. July 15, 2024) ("Plaintiffs' exclusive dealing claim rests on the same predicate as their tying claim. . . . Because the allegations of a negative tie fail [because plaintiffs had failed to adequately allege coercion, or a relevant market], so does the exclusive dealing claim.").

Where a supplier's "contractual language … provides for the possibility of purchasing" a secondary product from third-party sources, courts are "reluctant to find a tying arrangement without some evidence that [defendant] applied the contract language so restrictively as to constitute a de facto tying clause." *Photovest Corp.* v. *Fotomat Corp.*, 606 F.2d 704, 722 (7th Cir. 1979). A clause calling for a third party to be "authorized" does not amount to a tie, unless the possibility of "authorization" is "illusory" because the defendant will not actually authorize third parties in good faith. *Mozart Co.* v. *Mercedes-Benz of N. Am., Inc.*, 593 F. Supp. 1506, 1517 (N.D. Cal. 1984) (citing *United States* v. *Mercedes-Benz of N. Am., Inc.*, 517 F. Supp. 1369, 1383-84 (N.D. Cal. 1981)) (where defendant asks customers to work only with "authorized" third parties, there is no forcing or coercion unless the option for third parties to become authorized is "illusory"); *see also Ford Motor Co.* v. *GMB Universal Joints (West), Inc.*, 1988 WL 82826, at *3 (9th Cir. 1988) ("[a]n approval mechanism must not be illusory") (unpublished disposition) (citing *Mozart*, 593 F. Supp. at 1517).

Where the defendant "never refused a request to approve a supplier," a third-party authorization clause is not illusory and there is no tie. *Betaseed, Inc.* v. *U & I Inc.*, 681 F.2d 1203, 1224 (9th Cir. 1982) (citing *Kentucky Fried Chicken* v. *Diversified Packaging*, 549 F.2d 368, 373 (5th Cir. 1977)); *see also Pullos* v. *Alliance Laundry Sys., LLC*, 2009 WL 10708625, at *13 (N.D. Nev. 2009) (Ninth Circuit precedent "recognize[s] the important distinction between a seller coercing buyers to purchase supplies from the seller itself as opposed to from approved sources" and rejecting tying claim where customers were permitted to purchase from third parties that met the defendant's specifications). The defendant does not need to have published a list of authorized suppliers for the authorization clause not to be illusory. And, where the contract contains a third-party authorization clause, the plaintiff bears the burden of proving that the defendant in fact applied the clause so restrictively as to constitute a de facto tie. *Photovest*, 606 F.3d at 722.

Crucially, if the plaintiff never submitted a request for authorization to the defendant—as SIS did not here—that tends to undermine any effort by the plaintiff to prove that the authorization clause was illusory and that there was a tie. *Id.* ("Indeed, it appears that Photovest never submitted a processor to Fotomat for approval during this time period.").

Applying these principles to this case, SIS bears the burden of proving that Intuitive's third-party authorization clause was "illusory." Intuitive submits that SIS will be unable to meet this burden at trial. There is no evidence that Intuitive rejected authorization of third parties that actually met Intuitive's quality standards. And, there is unrebutted evidence that Intuitive permitted its customers to buy reset EndoWrists from third parties if they received clearance from the FDA. Furthermore, there is no evidence that SIS ever sought authorization from Intuitive, or made any attempt to secure FDA clearance or otherwise demonstrate to Intuitive through clinical evidence that the service that SIS offered was safe and effective.

As a result, SIS cannot establish the requisite "coercion" or "conditioning" element of a tying claim, and it cannot demonstrate that Intuitive engaged in exclusive dealing.

B. SIS Cannot Establish Substantially Less Restrictive Alternatives to Achieve Intuitive's Procompetitive Clinical and Business Objectives.

If SIS were able to establish a prima facie case of tying or exclusive dealing at trial, which it cannot do for the reasons discussed above, the burden would then shift to Intuitive to offer a procompetitive justification for seeking to discourage use of unauthorized third-party instruments. *See* Dkt. 204 at 17:12-20 (quoting *Ohio* v. *Am. Express Co.*, 585 U.S. 529, 541 (2018)) (other citations omitted). As the Court explained at summary judgment, a "procompetitive rationale is a 'nonpretextual claim that [defendant's] conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal.'" *Id.* at 17:25-27 (quoting *Fed. Trade Comm'n* v. *Qualcomm Inc.*, 969 F.3d 974, 991 (9th Cir. 2020)). And, as discussed above, at summary judgment, the Court credited "ensuring product reliability and minimizing risks to patients," as potential procompetitive justifications for Intuitive's alleged misconduct. *Id.* at 18:21-22. As the evidence at trial will show, EndoWrists are highly complex, and issues with modified EndoWrists can lead to serious patient harm. Intuitive has legitimate,

procompetitive reasons for requiring third-party authorization—including, most importantly, protecting patient safety, as well as ensuring product quality, promoting innovation, and protecting Intuitive's reputation and brand. The fact that Intuitive adopted the policies at issue here on Day One, before it had made a single sale of a da Vinci and when it could not have had market power, is also strong evidence that there is a good business justification for them.

SIS may rebut these procompetitive justifications only if it can demonstrate that a substantially less restrictive alternative exists to achieve Intuitive's procompetitive goals. "When evaluating proposed alternative means, courts 'must give wide berth to [defendants'] business judgments' and 'must resist the temptation to require that enterprises employ the least restrictive means of achieving their legitimate business objectives.'" *Epic*, 67 F.4th at 990 (quoting *Alston*, 594 U.S. at 102). "As such, this circuit's test—which the Supreme Court approved in *Alston*—requires a "*substantially* less restrictive" alternative." *Id.* (quoting *O'Bannon* v. *Nat'l Collegiate Athletic Ass'n*, 802 F.3d 1049, 1070 (9th Cir. 2015)). "To qualify as 'substantially less restrictive,' an alternative means 'must be virtually as effective in serving the [defendant's] procompetitive purposes . . . without significantly increased cost.'" *Id.* (quoting *O'Bannon*, 802 F.3d at 1074).

SIS cannot meet this burden. Rather, its claim amounts to saying that Intuitive should be prohibited from placing any restrictions at all on what third parties can do to the devices that Intuitive invented and that bear Intuitive's brand name on them. And the evidence will show there are no "virtually as effective" means as Intuitive's contract provisions, and enforcement thereof, for accomplishing Intuitive's procompetitive aims, including protecting patient safety.

C. Where SIS Has Taken No Steps Towards Authorization, SIS Cannot Establish Causation or Antitrust Injury.

A potential competitor seeking treble damages based on its alleged exclusion from a market must also show its alleged "damages were caused by the *unlawful* acts of the defendant." *MCI Commc'ns Corp.* v. *Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1161 (7th Cir. 1983). Although plaintiffs "need not rule out 'all possible alternative sources of injury,' they must show that the alleged anticompetitive activity was 'a material cause of the injury.'" *Catlin* v. *Washington Energy Co.*, 791 F.2d 1343, 1347 (9th Cir. 1986) (citation omitted). "However, if . . . that plaintiff's injury was

caused primarily by something other than the alleged antitrust violation, . . . that plaintiff has failed to prove that it is entitled to recover damages from defendant." *Discover Fin. Servs.* v. *Visa U.S.A., Inc.*, 582 F. Supp. 2d 501, 505 (S.D.N.Y. 2008) (citation omitted). Further, "[t]he trier of fact must be able to ascertain causal antitrust injury 'without engaging in speculation.'" *Catlin*, 791 F.2d at 1347 (citation omitted).

Intuitive has authorized FDA-cleared modified EndoWrists and indicated its willingness to consider clinical proof of safety and effectiveness provided by third parties, to ensure the safety and efficacy of third-party products or services used in connection with the da Vinci system. It was SIS's *choice* not to pursue these available paths to authorization, and thus SIS itself—not Intuitive's contracts or conduct—that caused SIS's sales to be lower than SIS wanted them to be. In addition, the evidence at trial will show that SIS misled its customers, mismanaged its business, and failed to invest in innovation or quality. SIS will be unable to prove that Intuitive's conduct, and not these other factors, was the material cause of its alleged damages.

Further, even if SIS were to prove anticompetitive conduct, it still must show an antitrust injury. "To have standing to bring an antitrust case, a plaintiff must demonstrate that the harm the plaintiff has suffered or might suffer from the practice is an 'antitrust injury,' that is, an 'injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.'" *Big Bear Lodging Ass'n* v. *Snow Summit, Inc.*, 182 F.3d 1096, 1102 (9th Cir. 1999) (quoting *Atl. Richfield Co.* v. *USA Petroleum Co.*, 495 U.S. 328, 334 (1990)). "[T]he antitrust laws . . . were enacted for 'the protection of competition not competitors.'" *Brunswick Corp.* v. *Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) (quoting *Brown Shoe Co.* v. *United States*, 370 U.S. 294, 320 (1962)). "The Supreme Court has made clear that injuries which result from *increased* competition or lower (but non-predatory) prices are not encompassed by the antitrust laws." *City of Oakland* v. *Oakland Raiders*, 20 F.4th 441, 457 (9th Cir. 2021) (quoting *Am. Ad Mgmt., Inc.* v. *Gen. Tel. Co. of Calif.*, 190 F.3d 1051, 1057 (9th Cir. 1999)). Thus, "[i]f the injury flows from aspects of a defendant's conduct that are beneficial or neutral to competition, there is no antitrust injury, even if the defendant's conduct is illegal." *Id.* (quoting *Theme Promotions, Inc.* v. *News Am. Mktg. FSI*, 546 F.3d 991, 1003 (9th Cir. 2008)).

Here, Intuitive's authorization requirement ensures the safety and efficacy of third-party products or services used in conjunction with the da Vinci system, which benefits consumers and competition as a whole. SIS complains about alleged injuries to *itself* as a competitor—namely, lost profits it allegedly could have made by selling unauthorized products and services—rather than any harm to competition. As a result, SIS cannot demonstrate antitrust injury.

Moreover, to demonstrate antitrust standing, a prospective competitor must "show a genuine intent to enter the market and a preparedness to do so." *Bubar* v. *Ampco Foods, Inc.*, 752 F.2d 445, 450 (9th Cir. 1985). SIS cannot meet this requirement either. "[A] potential competitor cannot achieve standing merely by demonstrating his intention to enter a field; he must also demonstrate his preparedness to do so." *Hecht* v. *Pro-Football, Inc.*, 570 F.2d 982, 994 (D.C. Cir. 1977). Preparedness requires taking affirmative, concrete steps toward entry, *id.*, which, here, includes seeking the necessary authorizations to compete in the market. SIS took no steps to secure the necessary authorization. Therefore it was not prepared to enter and lacks antitrust standing.

Finally, the antitrust laws do not reach "injury" stemming from the inability to sell *illegal* products. Thus, to establish a cognizable antitrust injury, SIS must prove that its business was lawful. *PharmacyChecker.com* v. *Nat'l Assoc. of Bds. of Pharmacy*, 2022 WL 347669, at *3 (S.D.N.Y. Feb. 4, 2022) ("Plaintiff bears the burden of proving that its business is legal."); *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 163-65 (3d Cir. 2017) (Plaintiff must show that it satisfied the legal requirements to engage in the business at issue).

Whether modifying EndoWrists to reset their use counters—as SIS, working with Rebotix, proposed to do—constitutes "remanufacturing," and would thus require 510(k) clearance from the FDA, is a factual issue that should be resolved by the jury. This was the conclusion reached by the court in *Restore Robotics, LLC* v. *Intuitive Surgical, Inc.*, No. 19-cv-00055 (N.D. Fla. Jan.). There, the court held that Intuitive's expert could not opine on the ultimate issue of "whether Plaintiff's 'repair' services required 510(k) clearance or that the FDA has definitively ruled on that issue." Ex. 7 at 4. But the court also indicated that the jury would be instructed that some activities require 510(k) clearance, such activities include "remanufacturing," and whether modifying EndoWrists to add additional uses requires 510(k) clearance depends on whether the jury

determines that such activities are "remanufacturing." Ex. 8 at 90:24-91:15, 94:7-17; *see also Restore*, 2022 WL 19408080, at *3 (N.D. Fla. Feb. 7, 2022) ("The role of the Court is to determine the law regarding 510(k) clearance and instruct the jury what was required of Plaintiffs under the law, and the role of the jury is to resolve any disputed questions of fact bearing on Plaintiffs' compliance (or not) with the law with the aid of any pertinent expert testimony regarding the complex regulatory scheme."). This conclusion should apply equally here.

Furthermore, if the jury were to conclude that modifying EndoWrists to change their usage limit constitutes remanufacturing, and therefore SIS was required to (but did not) seek 510(k) clearance from the FDA, then SIS cannot prove it has suffered an antitrust injury. *In re Can. Imp. Antitrust Litig.*, 470 F.3d 785, 791 (8th Cir. 2006) (antitrust claim dismissed where claimed injury was caused by FDA import restrictions and not defendants' conduct); *see also RSA Media* v. *AK Media Grp.*, 260 F.3d 10, 15 (1st Cir. 2001) (no antitrust injury where alleged injury stemmed from regulatory scheme that prevented plaintiff's construction of new billboards, rather than defendant's policy of tearing down billboards that were no longer being used); *see also Restore*, 2022 WL 19408080, at *4 ("[T]he Court tends to agree with Defendant that Plaintiffs will need to show that their repair work did not require 510(k) clearance in order to establish that their business was lawful and that any injury they suffered was caused by Defendant's anticompetitive conduct rather than the FDA's regulatory requirements." (citations omitted)).[8]

III. SIS CANNOT BASE ITS CLAIMS ON PROVISIONS THAT VOID WARRANTIES.

SIS attacks Intuitive contract provisions providing that use of unauthorized EndoWrists will void warranties, and Intuitive's enforcement of those provisions. But such provisions are not anticompetitive as a matter of law. Numerous courts have held contract provisions related to voiding warranties do not constitute tying arrangements. In *Marts* v. *Xerox, Inc.*, 77 F.3d 1109 (8th Cir. 1996), for example, a copy cartridge company sued Xerox for conditioning warranties on the use of replacement cartridges. The Eighth Circuit held this did not constitute an unlawful tying

[8] Intuitive recognizes the Court's summary judgment rulings that private parties do not have the authority to enforce the Food, Drug and Cosmetic Act or its implementing regulations, where, as here, FDA has not concluded that a violation exists, Dkt. 204:12:5-13:19, but nevertheless preserves this issue for a potential appeal.

arrangement. It explained that "a warranty is only *one* way of receiving service for a new Xerox copier." *Id*. at 1112 (emphasis added). An owner of a new Xerox copier thus "could forego the benefits of the warranty, buy service from Xerox or an independent provider, and purchase cartridges from the vendor of its choice." *Id*. Whatever the decision, the "end result is the same: customers receive both service and cartridges for their copiers." *Id*. And since no evidence precluded a finding that customers could purchase Xerox service from the service maintenance agreement or on a time and materials basis, the Eighth Circuit concluded, customers had alternatives *other* than purchasing the items together. Similarly, the Federal Circuit has found that "threats to void or limit warranties" do not constitute anti-competitive conduct, and specifically do not constitute tying, because "voiding a warranty on a product already sold, while possibly a breach of warranty, cannot be a tying arrangement because the purchaser is not deciding whether to buy a product." *Virginia Panel Corp.* v. *MAC Panel Co.*, 133 F.3d 860, 870 (Fed. Cir. 1997). *See also Fido's Fences* v. *Canine Fence Co.*, 672 F. Supp. 2d 303, 312 (E.D.N.Y. 2009) (holding that "it is well settled that warranties that are not sold as a separate product do not result in consumer coercion if the warranty sets forth requirements").

The fact that customers chose warranty service over alternatives is not anticompetitive; it is customer choice. Courts have also held such provisions are not anticompetitive in the context of other Section 1 claims. In *Hobart-Mayfield, Inc.* v. *Nat'l Oper. Comm. on Standards for Athletic Equip.*, 48 F.4th 656 (6th Cir. 2022), plaintiff alleged various Section 1 claims based on a helmet manufacturer's threats to void helmet warranties if customers used unauthorized add-on products. The Court held the manufacturer could avoid antitrust liability by pointing to a "legitimate business interest." *Id*. at 669-70. Because the helmet manufacturer served a "market that places high regard on the safety and warranty of its products," it could meet that mark by showing a "desire to protect their reputations and sell safe products." *Id*.

As in each of these cases, Intuitive's contracts with hospitals stipulated, and have always stipulated, that the use of unauthorized third-party services may void warranties. *See also HDC Medical, Inc.* v. *Minntech Corp.*, 474 F.3d 543 (8th Cir. 2007) (refusal of a manufacturer of reprocessing machines to honor one-year warranties if customers used competitors' reprocessing

solution was not anticompetitive; since manufacturer could not "predict how its machines would react" to competitors' solutions, the court held it was right to "believe[] that it could not feasibly warrant the performance of the product"). SIS's claims related to voiding warranties thus fail as a matter of law, and cannot give rise to any cognizable antitrust injury or damages.

IV. SIS'S MONOPOLIZATION CLAIM BASED ON INTUITIVE'S RE-DESIGN OF ITS X/XI ENDOWRIST IS FORECLOSED BY *ALLIED ORTHOPEDIC*.

The design changes that Intuitive implemented when it introduced its X/Xi model EndoWrists, which had numerous customer benefits, cannot be the basis for antitrust liability. As this Court recognized, "[t]o count as unlawful exclusionary conduct, a firm must not have had any 'procompetitive justification' for its design change." Motion to Dismiss Order, Dkt. 70 at 8 (quoting *Allied Orthopedic*, 592 F.3d at 998).[9] In *Allied Orthopedic*, the plaintiff alleged that, by moving a digital memory chip from a monitor to a sensor, defendant made it impossible for competitors' monitors to work with defendant's sensors. 592 F.3d at 994. Defendant there demonstrated a procompetitive clinical reason for its new product design, but plaintiff argued that the anticompetitive effects outweighed the procompetitive ones. *Id.* at 999-1000. The Ninth Circuit rejected the plaintiff's argument, explaining that once a defendant establishes that its medical device design serves a procompetitive reason, "[t]here is no room . . . for balancing the benefits or worth of a product improvement against its anticompetitive effects" and the design "*is necessarily tolerated by the antitrust laws*." *Id.* at 1000 (internal quotations omitted) (emphasis added). This is true even if the design change "is performed by a monopolist and harms competitors as a result." *Id.* at 999-1000.

Here, the evidence will show that the design changes from S/Si to X/Xi EndoWrists have numerous benefits, including increased reliability against physical damage. The RFID chips used in X/Xi EndoWrists, as compared to the earlier chips, have increased memory, faster data access, and improved reliability and endurance. To the extent the jury agrees there is any procompetitive justification, Intuitive cannot be held liable for this design change.

[9] The Court held that *Allied Orthopedic* did not warrant dismissal, only because SIS alleged there was no "procompetitive justification" for the X/Xi EndoWrist design change—the truth of which is to be assumed on a motion to dismiss. Dkt. 70 at 8.

V. SIS CANNOT SHOW THAT INTUITIVE IS A MONOPOLIST IN ANY PROPERLY DEFINED RELEVANT MARKET.

"[A] threshold step in any antitrust analysis is to accurately define the relevant market." Dkt. 204 at 17:3-4 (citing *Am. Express*, 585 U.S. at 543). SIS has alleged that Intuitive has market power in two (and only two) markets: "the market for minimally invasive soft tissue surgical robots" ("MIST robots") and "the market for replacements and repairs of Endo Wrists." Ex. 9, Dec. 2, 2022 Expert Report of Dr. Russel L. Lamb, at 2.[10]

A. SIS Cannot Establish That Intuitive Has Market Power in the Properly Defined Market in Which Intuitive Competes, Which Includes Other Surgical Modalities.

1. Da Vinci Systems Compete Against Other Surgical Modalities.

The parties have agreed the relevant geographic market is the United States. It will be up to the jury to define the relevant product market. As the Court explained at summary judgment in *In re Da Vinci Surgical Robot Antitrust Litig.*, No. 21-cv-03825 (N.D. Cal):

> A product market consists of the product at issue and all economic substitutes for that product. *Newcal Indus., Inc.* v. *Ikon Off. Sol.*, 513 F.3d 1038, 1045 (9th Cir. 2008). "Economic substitutes," the Ninth Circuit states,
>
> > have a "reasonable interchangeability of use" or sufficient "cross-elasticity of demand" with the relevant product. Including economic substitutes ensures that the relevant product market encompasses "the group or groups of sellers or producers who have actual or potential ability to deprive each other of significant levels of business."
>
> *Hicks* v. *PGA Tour, Inc.*, 897 F.3d 1109, 1120 (9th Cir. 2018) (internal citation omitted). Determining the relevant market is typically a fact-intensive inquiry, involving "identification of the field of competition: the group or groups of sellers or producers who have actual or potential ability to deprive each other of significant levels of business." *Thurman Indus., Inc.* v. *Pay 'N Pak Stores, Inc.*, 875 F.2d 1369, 1374 (9th Cir. 1989).

In re Da Vinci, Dkt. 232 at 14:16-15:2. In *In re Da Vinci*, the Court rejected the plaintiffs' motion

[10] *Id.* ("I understand from Counsel for the Plaintiff that Plaintiff's allegations in this matter relate to Intuitive's dominance of the market for minimally invasive soft tissue surgical robots . . . with its da Vinci surgical robots, and that, through exclusionary and anticompetitive conduct, Intuitive uses this dominance to maintain its monopoly in a separate market: the market for replacements and repairs of Endo Wrists, which are surgical instruments (e.g., graspers, forceps, scissors, etc.) that are used during the da Vinci robotic surgeries").

on this issue, holding that, based on the record at summary judgment, "there exist[ed] a genuine dispute as to whether surgical robots constitute a distinct market that can be separated from laparoscopy and open surgery." *Id.* at 16:2-4. Contrary to SIS's myopic market definition, narrowly defined to include only "MIST surgical robots," the evidence at trial will show that the da Vinci always has competed and continues to compete with laparoscopic and open surgery, as customers substitute laparoscopic or open for da Vinci surgery. Hospitals compare the outcomes and the cost of da Vinci surgery against the outcomes and cost of open and laparoscopic surgery, and Intuitive markets the da Vinci by showing hospitals that da Vinci surgery is better for patients and more cost effective on a per-procedure basis against open and laparoscopic surgery. At a minimum, the relevant market should be defined to include laparoscopy as an alternative to da Vinci for performing minimally invasive soft-tissue surgeries.

2. Intuitive Does Not Have Market Power in Any Market That Includes Other Surgical Modalities.

"Market power is the power 'to force a purchaser to do something that he would not do in a competitive market.' It has been defined as 'the ability of a single seller to raise price and restrict output.' The existence of such power ordinarily is inferred from the seller's possession of a predominant share of the market." *Kodak*, 504 U.S. at 464 (citations omitted). SIS does not even contend that Intuitive has market power in any market other than the one that SIS narrowly and incorrectly defines. Further, the evidence will show that da Vinci procedures only account for a small fraction of all procedures in the properly defined market that includes other surgical modalities. Laparoscopic and open surgery are still twice as common as da Vinci surgery. For many procedures, da Vinci's share is even lower. The evidence will also show that Intuitive is competitively constrained by hospitals' and doctors' ability to substitute with laparoscopic or open surgery. In addition to competing with laparoscopic and open on total, all-in procedure costs, as discussed above, Intuitive has also developed flexible financing terms for hospitals to increase its price competitiveness, including a leasing program, to reduce the upfront capital investment of acquiring a da Vinci system, and per-use payment options for hospitals, with no penalty for hospitals if they do not meet expected use levels.

B. Under Controlling Ninth Circuit Precedent, SIS Must Satisfy the *Epic* Factors to Establish a Single-Brand Aftermarket Regardless of Its Allegations that Intuitive Has Market Power in the Alleged Foremarket for MIST Robots.

With respect to its tying claim, SIS has alleged an aftermarket for EndoWrist repair and replacement. *See* Compl., Dkt. 1 ¶ 10; Dkt. 230-04 at 2. These allegations should fail because Intuitive designed and markets the da Vinci system, including EndoWrists, as one integrated surgical *system—i.e.*, a single product. SIS cannot establish that EndoWrists are in a different relevant market from the da Vinci itself. Furthermore, even if SIS could clear the hurdle of establishing two separate products, as the Court is aware, there is an open issue about the application of *Epic* to SIS's alleged aftermarket definition. *See generally* Dkt. 252-2; 257-1.

Generally, the law forbids antitrust plaintiffs from defining a market around the defendant's own brand of products. In *Epic*, the Ninth Circuit held:

> [T]o establish a single-brand aftermarket, a plaintiff must show: (1) the challenged aftermarket restrictions are "not generally known" when consumers make their foremarket purchase; (2) "significant" information costs prevent accurate life-cycle pricing; (3) "significant" monetary or non-monetary switching costs exist; and (4) general market-definition principles regarding cross-elasticity of demand do not undermine the proposed single-brand market.

67 F.4th at 977. Although the court stated this rule categorically and without any exception, SIS will argue that the *Epic/Kodak* factors do not apply when the defendant has market power—or, alternatively, perhaps monopoly power, or perhaps a "near-total monopoly"—in the primary market (which, as discussed above, SIS alleges to be a market limited to MIST surgical robots).

The reason for SIS's effort to import a market power limitation on *Epic's* four-part test for single-brand aftermarkets is clear. If *Epic* applies, there is no evidence in the record with which SIS could satisfy it. To the contrary, the evidence shows that the challenged restraints were clearly disclosed before hospitals made their investment decisions and that hospitals are sophisticated entities that engage in lifecycle pricing with respect to MIST robotic systems. SIS thus cannot satisfy at least the first and second prongs of *Epic*'s four-factor test for establishing a single-brand market, and *Epic* makes clear that proof of all four prongs is required.

As noted, SIS argues that *Epic* does not apply because Intuitive has market power in the alleged market for MIST robots. Intuitive disputes that it has market power in any properly defined

relevant market. In any event, it is not the law in this Circuit that the *Epic/Kodak* factors do not apply if the defendant has market power in the primary market. To the contrary, the Ninth Circuit has applied the *Epic* factors to affirm dismissal of a complaint in which the plaintiff alleged monopoly power in the primary market, but failed to plead the *Epic/Kodak* factors. *See Coronavirus Reporter* v. *Apple, Inc.*, 85 F.4th 948 (9th Cir. 2023). The complaint there alleged explicitly that Apple (the defendant) had a market share of 60-80% and "operates a *de facto* monopoly for smartphone internet access devices," which was one of two foremarkets that plaintiffs asserted as a predicate to pleading a single-brand aftermarket.[11] Plaintiffs also alleged an alternative foremarket for U.S. iOS devices, in which they asserted that Apple is a total monopolist. *Coronavirus Reporter*, 2021 WL 5936910, at *3 (N.D. Cal. Nov. 30, 2021); *see* Ex. 10 ¶¶ 11, 18, 234. The Ninth Circuit affirmed dismissal of the complaint on two grounds: First, Plaintiffs had pled relevant markets in a too "scattergun fashion." 85 F.3d at 956. Second, and independently, "Plaintiffs-Appellants did not allege the prerequisites for a single-brand market. For example, Plaintiffs-Appellants do not demonstrate that iOS end consumers lacked awareness that buying an iPhone constrains which apps would be available to them through the App Store." *Id.* In other words, the court dismissed a single-brand aftermarket claim for failure to satisfy the *Epic* factors even though Apple was alleged to have either a 60-80% or 100% market share in the foremarkets.[12] If the *Epic/Kodak* factors do not apply when the plaintiff alleges that the defendant has market power or a monopoly in a primary market, *Coronavirus Reporter* would have been the case to say it. The Ninth Circuit said the opposite.

Although post-*Kodak* cases sometimes speak about the foremarket being competitive or the defendant lacking market power in that market, that is only because of the particular way that issue arose in *Kodak*. In *Kodak*, there were three markets at issue: (1) the primary market for

[11] Ex. 10 ¶ 11 ("Nearly 60% of U.S. internet users and 80% of paid internet commerce access the national internet backbone using Apple devices. For these users, their access to the internet relies upon using an iOS device. As such, Apple operates a de facto monopoly for smartphone internet access devices. Downstream from this market is the national smartphone app distribution market, of which Apple's App Store controls 80% of app revenue.").

[12] That the *Epic* reason for affirming dismissal was additional to the "scattergun pleading" reason does not diminish its binding authority. *United States* v. *Brown*, 996 F.3d 998, 1010 (9th Cir. 2021) ("[W]here a decision rests on two or more grounds, none can be relegated to the category of obiter dictum.") (citation omitted).

copier machines; (2) an aftermarket for parts for Kodak copiers; and (3) an aftermarket for service for Kodak copiers. *Id.* at 459 ("Respondents allege a tying arrangement not between Kodak equipment and service, but between Kodak parts and service."). The plaintiffs did not argue that Kodak had market power in the primary market for copier machines—it was undisputed that the primary market was competitive. Kodak argued that "because competition exists in the equipment market … it could not have the ability to raise prices of service and parts above the level that would be charged in a competitive market because any increase in profits from a higher price in the aftermarkets at least would be offset by a corresponding loss in profits from lower equipment sales as consumers began purchasing equipment with more attractive service costs." *Id.* at 465. In a 5-4 decision, the Supreme Court rejected that argument, holding that "there is no immutable physical law—no 'basic economic reality'—insisting that competition in the equipment market cannot coexist with market power in the aftermarkets." *Id.* at 471. Because *Kodak* may have adopted its tying policy after customers purchased their copiers, customers may not have been able to engage in lifecycle pricing, and switching prices may have been high, it was possible that Kodak could exploit its customers in the services aftermarket even though it lacked market power in the primary market for copiers. *Id.* at 473-77.

The *Kodak* Court made its comments about competitiveness of the foremarket in answering an argument made by Kodak. It did *not* hold that the factors it discussed—which subsequently became the basis for the four-prong *Epic* test—apply only where the defendant lacks market power in the foremarket. Nor have courts since *Kodak* taken the decision to mean that. To the contrary, courts like *Coronavirus Reporter* have applied the *Epic/Kodak* factors even when the defendant was alleged to have market power or even a total monopoly in the foremarket.

The approach suggested by SIS—disregarding the *Epic/Kodak* factors when the defendant is alleged to have market power in the primary market—would be inconsistent with fundamental principles of tying law. As noted above, in every tying case, "the plaintiff must prove that the defendant has market power in the tying product." *Ill. Tool Works*, 547 U.S. at 46. In *Kodak*, importantly, the primary market was not the tying market—the tying market was the aftermarket for parts. But in many tying cases, such as *Coronavirus Reporter*, the primary market *is* the tying

market. If SIS's argument were correct, then plaintiffs would receive an automatic exemption from *Epic* whenever the primary market was also the tying market and therefore one in which the defendant allegedly has market power. But that position has been rejected by *Coronavirus Reporter* and other decisions, which apply the *Epic* factors in circumstances where the primary market is also the tying market, and market power is therefore necessarily present.

For instance, in *Blizzard Entertainment Inc.* v. *Ceiling Fan Software LLC*, 941 F. Supp. 2d 1227 (C.D. Cal. 2013), the counter-claimant alleged that Blizzard, the maker of the popular computer role-playing game World of Warcraft ("WoW"), unlawfully tied "the sale of its WoW software on the condition that users of WoW will not purchase any unauthorized third-party hardware or software." *Id.* at 1230. Blizzard allegedly had a market share of at least 62% of the "multiplayer online role-playing game market," *id.*, and, as in *Coronavirus Reporter* and this case, that tying market was the primary market for *Kodak* purposes. Under SIS's argument, since Blizzard had market power in the primary market, the *Epic/Kodak* factors should not have applied, but the court held the contrary. Unlike in *Kodak*, customers were aware of the contractual restriction on aftermarket use of third-party software at the time they signed up for WoW and there were no market imperfections that disabled them from understanding the significance of those restrictions; therefore, there was no permissible single-brand aftermarket. *Id.* at 1236.[13]

SIS may try to rely on *Lambrix* v. *Tesla, Inc.*, 2024 WL 3403777 (N.D. Cal. June 17, 2024) for the proposition that a plaintiff need not satisfy the *Epic/Kodak* factors when the defendant has market power in the primary market. For the reasons discussed above, the *Lambrix* court erred in turning statements in *Kodak* and other cases in which the primary market is not the tying market into a general rule that that defendant must not have market power in the tying market for the *Epic/Kodak* factors to apply. The court also failed to consider the Ninth Circuit's *Coronavirus*

[13] Other courts have similarly applied the *Epic/Kodak* factors but found them satisfied in circumstances when the defendant had monopoly power in the primary market. *See In re Dealer Mgt. Sys. Antitrust Litig.*, 313 F. Supp. 3d 931, 937, 939, 961-64 (N.D. Ill. 2018) (defendants had collective market share of 75% of dealer-management system market and forced customers to buy data-integration after-market services from defendants; plaintiff adequately alleged single-brand aftermarkets because they satisfied the *Kodak* elements).

Reporter decision, in which the court affirmed dismissal of a complaint on *Epic/Kodak* grounds even though the plaintiff alleged monopoly power in the primary market.

Moreover, the *Lambrix* court made a fundamental mistake in believing that the presence of market power in the primary market means that purchasers cannot enter into knowing and voluntary contracts with the defendant. *Newcal Indus.*, 513 F.3d at 1048 ("the law prohibits an antitrust claimant from resting on market *power* that arises solely from contractual rights that consumers knowingly and voluntarily gave to the defendant"). SIS claims that Intuitive has a monopoly over MIST robots and charges a monopoly price. When a company charges a monopoly price, customers consider other products to be substitutes that might not have been good substitutes at a lower price. *See United States* v. *Eastman Kodak Co.*, 63 F.3d 95, 105 (2d Cir. 1995). As Judge Learned Hand explained in *Alcoa*, 148 F.2d at 426, "substitutes are available for almost all commodities, and to raise the price enough is to evoke them." If Intuitive is charging a monopoly price, what constrains it from charging an even higher price is that hospitals would switch to other forms of surgery.[14] Thus, hospitals that purchase da Vincis at monopoly prices (assuming SIS's theory), with knowledge of the challenged restrictions and with the capacity to engage in lifecycle pricing, are doing so after considering alternatives and are making a knowing and voluntary choice.

C. SIS Has Not Pled a Relevant Market for Servicing da Vinci Systems.

To the extent that SIS contends that Intuitive has, and has leveraged, market power in any relevant market for the servicing of da Vinci systems, as its recent filings suggest it may try to do, *see* Joint Proposed Final Pretrial Order, Dkt. 278, SIS's Description of Its Claims ("Intuitive has used its monopoly power in the minimally invasive soft tissue ('MIST') surgical robot market, in the separate EndoWrist instrument replacement aftermarket*, as well as in the servicing of its da Vinci MIST surgical robots*, to engage in a variety of anticompetitive practices resulting in an unlawful restraint of trade."), SIS cannot establish the relevant market for such a claim.

First, for the same reasons discussed above, SIS cannot establish a single-brand aftermarket for servicing da Vinci robots. Additionally, SIS retained an expert to opine on market definition,

[14] As the hospitals' expert, Professor Elhauge, has admitted, there is "substitution at the margin" between MIST robots and other forms of surgery—meaning that given Intuitive's alleged monopoly prices, hospitals do substitute to other forms of surgery.

and that expert, Dr. Lamb, opined that there were only two relevant potential markets: a market for "MIST surgical robots" and a market for "Endo Wrist Repair and Replacement." *See* Ex. 9 at 2. Unlike cases in which courts have declined to dismiss claims for failure to present any expert testimony on market definition, *e.g.*, *Sidibe* v. *Sutter Health*, 2019 WL 2078788, at *26 (N.D. Cal. May 9, 2019), here, SIS disclosed an expert on market definition, that expert affirmatively opined there were only two markets, and Intuitive relied on that in preparing its expert rebuttal to SIS's asserted market definitions. SIS should not now be allowed to change course and argue there is yet another relevant market, whether through Dr. Lamb's testimony or otherwise. The Federal Rules of Civil Procedure regarding expert disclosure were intended to avoid such gamesmanship. *See Mailhoit* v. *Home Depot U.S.A., Inc.*, 2013 WL 12122580, at *3 (C.D. Cal. Jan. 24, 2013) ("'[t]he rules of discovery were not designed to encourage procedural gamesmanship,' but rather to ensure the disclosure of information regarding expert testimony sufficiently in advance of trial such that opposing parties have a reasonable opportunity to prepare for effective cross-examination and perhaps to arrange for expert testimony from other witnesses." (quoting *Roch* v. *Mormac Marine Transp., Inc.*, 1995 WL 479426 at *3 (S.D.N.Y. 1995)).

VI. SIS CANNOT ESTABLISH ITS CLAIMED DAMAGES ARE THE RESULT OF INTUITIVE'S ALLEGED MISCONDUCT.

SIS cannot prove that it is entitled to recover the damages it claims. The goal of antitrust damages is to "put a plaintiff forward into the position it would have been 'but for' the defendant's violation of the law," *L.A. Memorial Coliseum Comm'n* v. *NFL*, 791 F.2d 1356, 1367 (9th Cir. 1986), while "holding every other feature of the *actual world* constant." Am. Bar Ass'n, *Proving Antitrust Damages: Legal and Economic Issues* pt. II, ch. 4.B (3d ed. 2017) (emphasis added). This requires the plaintiff to "disaggregate" losses caused by the defendant's alleged illegal conduct, if any, from losses "caused by acts which were not antitrust violations." *City of Vernon* v. *S. Cal. Edison Co.*, 955 F.2d 1361, 1372 (9th Cir. 1992). That is, "the plaintiff's damages claim must . . . exclude losses caused by other factors," including "plaintiff's own conduct, such as poor management or missed opportunities," or "other marketplace factors, such as changes in customers' demand, entry by other competitors, or changes in product technology." *Proving*

Antitrust Damages, pt. III, ch. 9.C.1.b. When the plaintiff fails to carry its burden to disaggregate, "it [is] impossible for a jury to estimate the lost profits attributable to [the defendant's] conduct." *Magnetar Techs. Corp.* v. *Intamin, Ltd.*, 801 F.3d 1150, 1160 (9th Cir. 2015); *see City of Vernon*, 955 F.2d at 1372 (Plaintiff's "utter failure to make any segregation between damages attributable to lawful competition and that attributable to the unlawful scheme . . . requires reversal of the verdict and remand for a new trial on the amount of damages." (internal citation omitted)). The plaintiff "must provide evidence such that the jury is not left to speculation or guesswork in determining the amount of damages to award." *McGlinchy* v. *Shell Chem. Co.*, 845 F.2d 802, 808 (9th Cir. 1988) (citation and internal quotations omitted).[15]

SIS's damages expert, Richard Bero, fails to present a model by which jurors could disaggregate losses resulting from allegedly unlawful conduct from those resulting from other factors. Those factors include, among other things, SIS's own choices not to independently prove its product safe, not to seek authorization from Intuitive to modify EndoWrists, not to seek FDA clearance, and not to develop the technology needed to reset X/Xi EndoWrists, as well as SIS's general mismanagement of its business and Intuitive's lawful competitive conduct. Further, SIS deliberately refused to engage in discovery for the post-November 2022 period, and has since admitted that it did nothing to even try to compete during that period. Ex. 11 at 3-5.

Thus, in short, the undisputed record now shows that SIS voluntarily shut down its EndoWrist "repair" business years ago, has done nothing to pursue opportunities that other third parties in the same alleged "market" have been pursuing, and now comes to Court asking for hundreds of millions of dollars in "damages" caused by its own choice not to compete. The antitrust laws do not permit any such windfall recovery.

VII. INTUITIVE MAINTAINS MULTIPLE COUNTERCLAIMS AND AN AFFIRMATIVE DEFENSE, FOR MISCONDUCT BY SIS.

Intuitive asserts three counterclaims: (1) that in marketing materials and communications to potential and actual customers, SIS made false and misleading statements and engaged in unfair

[15] Am. Bar Ass'n, *Model Jury Instructions in Civil Antitrust Cases*, ch. 6.B, Instruction 4 (2016) ("If you find that there is no reasonable basis to apportion plaintiff's alleged injury between lawful and unlawful causes, or that apportionment can only be accomplished through speculation or guesswork, then you may not award any damages at all.").

competition in violation of the Lanham Act, 15 U.S.C. § 1125; (2) that SIS engaged in deceptive and fraudulent conduct with the intent to confuse and deceive the public into using its service and purchasing modified EndoWrists, which constitutes unfair competition under California law; and (3) that SIS tortiously interfered with Intuitive's contractual relationships with its customers, in violation of California law. Intuitive also raises an affirmative defense that SIS's claims are barred, in whole or in part, by the doctrine of unclean hands because of SIS's misconduct.

Per the Court's summary judgment ruling and order entering the parties' joint stipulation regarding the scope of that ruling, these counterclaims and affirmative defense were limited only to the extent that they relate specifically to "SIS's representations that Section 510(k) clearance was not necessary," "regulatory interpretation left to the FDA in the first instance" or "proving a violation of the FDCA . . . or that SIS 'violated FDA regulations.'" Dkt. 240 at 1:15-23 (quoting Dkt. 204 at 13:10-13; 13:17; 14:11-17). They were not dismissed to the extent they relate to other conduct, including disseminating marketing materials and communications that misrepresent:

- The nature, efficacy, and/or safety of the service SIS coordinates (e.g., by referring to those services as "repairs" or similar terms);
- That "repaired" EndoWrists meet applicable quality and functional requirements;
- That devices "serviced" through SIS meet 'original specifications' of EndoWrists and are safe to use;
- That SIS itself developed, has tested and conducts the "repairs;"
- That use of the service will result in substantial cost savings;
- That use of the service does not carry any adverse financial, legal or other consequences (*e.g.*, voiding Intuitive customers' warranties);
- That use limits built into EndoWrists are "arbitrary" or Intuitive otherwise is not trustworthy; and
- That SIS and/or the service it offers is authorized or approved by Intuitive.

See Intuitive's Answer, Affirmative Defense and Counterclaims, Dkt. 75 Counterclaim ¶ 85, (i)-(iv), (vi)-(ix). Intuitive seeks damages and equitable relief for SIS's misconduct.[16]

[16] Such misconduct may also include returning to customers different and/or superior instruments "but passing off those products as genuine Intuitive EndoWrists," "[t]he resulting confusion as to the source or affiliation of the 'repaired' instruments is exacerbated by SIS's communications that also leverage Intuitive's trademarks and misinform customers that 'a repaired EndoWrist® is not an alternative or replacement device' but rather 'an original da Vinci® manufactured device that has been repaired to original specifications.'" Dkt. 75 Counterclaim ¶ 86. Such conduct may also include other "intentional acts to disrupt [Intuitive's contracts] and/or induce Intuitive customers to breach them." Dkt. 75 Counterclaim ¶ 85.

Dated: October 28, 2024

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CERTIFICATE OF SERVICE

On October 28, 2024, I caused a copy of Defendant's Trial Brief to be electronically filed via the Court's Electronic Case Filing System and served via email on counsel of record for Surgical Instrument Service Company, Inc.

Dated: October 28, 2024

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